K121724

Revision 08-21-2012

SEP 20 2012

510(k) Summary

Submitter:			Date of Preparation: June 08, 2012
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
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City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: 60061
Contact name: Mr. Ron Haselhorst			
Contact title: Quality Assurance / Regulatory Affairs Manager			
Parent Company:			
Company / Institution name: **Richard Wolf GmbH**			FDA establishment registration number: 96 111 02
Street address: Pforzheimer Str. 32			
City: Knittlingen	State/Province: Baden-Württemberg	Country: Germany	ZIP / Postal Code: 75438
Product Information:			
Trade name: 5160 ENDOLIGHT LED Light Source		Model numbers: 5160XXX	
Common name: LED Light Source		Classification name: FCW – Light Source, Fiber Optic, Routine NTN – LED Light Source	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K983628	1 Auto LP 5123 Xenon Light Projector (Product Code GCT)	1 Richard Wolf Medical Inst. Corp.
2 K082813	2 Stryker LED Light Source (Product Code FCW)	2 Stryker Endoscopy
3 K102167	3 LO-50 LED Light Source (Product Code FCW, NTN)	3 Fiberoptics Technology, Inc

Device Description:

The ENDOLIGHT LED Light Source is a fiber optic light source utilizing a single, solid state, high power, white light emitting diode (LED) to produce visible light that used to illuminate surgical sites during minimally invasive surgical procedures. The light from the ENDOLIGHT LED Light Source is transmitted through an optical cable and a scope.

ENDOLIGHT LED 1.1 and 1.2 are comprised of light source and power supply cord. The units consist of aforementioned LED, cooling fan, light port, and protective housing.

ENDOLIGHT LED 1.1 and 1.2 are portable and are very similar in design, format, and functionality to other LED light sources including the predicate devices.

This product is exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately trained persons.

Intended Use:

The ENDOLIGHT LED Light Source Projector is intended to be used to illuminate the surgical site during minimally invasive surgical procedures by producing light that is transmitted from the light source through fiber optic cable and a scope.

Technological Characteristics:

The ENDOLIGHT LED Light Sources 1.1 and 1.2 are technologically similar to predicate device found in this submission in that all/some of the devices:

- Use fiber optic cables and scopes to transmit the light from the source to the site of the medical procedure
- Use an identical technology ie, an LED lamp to produce light while others use an equivalent source such as a xenon or halogen lamp.
- Utilize similar manual controls to set the light brightness
- Have similar illumination and quality of light
- Operate within an equivalent temperature range
- Can utilize a number of commonly available fiber optic cables
- ENDOLIGHT LED 1.2 has a light cable detection feature which shuts the unit off the LED lamp when the fiber optic cable is detached reducing the chance of unit overheating.

The ENDOLIGHT LED Light Sources are technologically different to predicate devices found in this submission in that:

- ENDOLIGHT LED 1.2 utilizes a "Safe Start"™ function which after a power interruption of more than five seconds and less then thirty seconds the LED lamp is shut off but retains nominal brightness setting. After thirty seconds the LED lamp is shut off and brightness is reset to 50%.

Performance Data:

Design verification testing demonstrates that the devices function as intended, and the performance did not raise any new issues of safety and effectiveness, and that formal user training is not required.

Voluntary Safety and Performance Standards: The ENDOLIGHT LED 1.1 and 1.2 conform to the following Safety Standards:

- IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (General)
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- IEC 60601-2-18:1996, Amendment 1 2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment. (Dental/ENT)

Testing was completed by Independent laboratories, certifications are on file.

Clinical Data:

No clinical tests performed.

Rational for Substantial Equivalence:

The Richard Wolf ENDOLIGHT LED Light Source shares the same general indications for use, has similar function features and technological characteristics as the predicate devices, the minor difference(s) do not raise new questions for safety or effectiveness.

The Richard Wolf ENDOLIGHT LED Light Sources were non-clinically tested to determine the safety and efficacy under the indications for use and meet aforementioned safety standards, same as the predicate devices.

For these reasons, the Richard Wolf ENDOLIGHT LED Light Source is substantially equivalent to the existing 510(k) cleared devices sold by: Richard Wolf Medical Instruments Corporation (K983628), Stryker Endoscopy (K082813), and Fiberoptics Technology, Inc (K102167).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

Mr. Ron Haselhorst
Quality Assurance / Regulatory Affairs Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K121724
Trade/Device Name: ENDOLIGHT LED Light Source
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCW, NTN
Dated: August 22, 2012
Received: August 27, 2012

Dear Mr. Haselhorst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K121724

Device Name: ENDOLIGHT LED Light Source

Intended Use:

The ENDOLIGHT LED Light Source Projector is intended to be used to illuminate the surgical site during minimally invasive surgical procedures by producing light that is transmitted from the light source through fiber optic cable and a scope.

Prescription use ✓ (Part 21 CFR 801 Subpart D) and / or Over-The Counter Use _____ (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ANOTHER PAGE IF NEEDED

Concurrence of CDHR office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121724